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BRANDON N. SKLAR, ESQ.
MORGAN & FINNEGAN, LLP
345 PARK AVE
NEW YORK NY 10154-0053

EXAMINER	
DASTOURI, M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/032,450	Applicant(s) Gutkowicz-Krucin et al
	Examiner Mehrdad Dastouri	Group Art Unit 2723

☒ Responsive to communication(s) filed on *Feb 10, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-79* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) *6 and 68-72* is/are allowed.

☒ Claim(s) *1-3, 7, 10-36, 41, 42, 44-58, 61, 62, 65-67, and 73-79* is/are rejected.

☒ Claim(s) *4, 5, 8, 9, 37-40, 43, 59, 60, 63, and 64* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed, February 10, 2000, has been entered and made of record.

2. Objection to Claims 41 and 42 has been withdrawn in view of the Applicants' amendment.

3. Applicants' arguments with regards to Claims 1, have been fully considered but they are not persuasive.

Regarding Claim 1, Applicants argue in essence that prior art of record (Cabib et al, U.S. 5,784,162) teaches away from the method of the present invention by referring to Column 3, Lines 29-34 of this prior art. The Examiner disagrees and indicates that the part referred to by Applicants is related to "field and background of the invention", wherein Cabib et al explains the deficiency of the related arts. Cabib et al further discloses the advantages of their invention over these deficiencies as detailed in Column 3, Lines 65-67, Column 4, Lines 1-46. In fact, Cabib et al teachings of utilizing a spectral image in a three dimensional array of data, I (x, y, λ), that combines spectral information with spatial organization of the image, is exactly analogous to Applicants' invention disclosed on Page 30, Lines 23-25 through Page 31, Lines 1-15 (Formula 6). Regarding Applicants further arguments on Page 13, Lines 6-13, concerning the extent of Cabib et al patent broadness wherein "the patent attorney describes the entire world encompassed ....", the examiner indicates that there is no requirement to limit any attorney/applicant claimed invention. Concerning Applicants argument on Page 13, Line 14 through Page 15, Line 12; the Examiner asserts that Claim 1 only cites "characterizing a skin lesion", and does not limit the

claimed invention to "in vivo imaging of macroscopic lesions".

Applicants further argue that the values disclosed by Lee et al (secondary prior art) are not related to the estimated values referred to in the Claim 1 such as "computes at least one estimated value for each digital image at each spectral band which is a function of a characteristic of the portion of the region of interest determined by the segmentation mask" **in the sense of the specification**. The Examiner disagrees and asserts that in Lee et al teachings, the intensity values of the pixels for each digital image at each spectral band are reasonable interpretation of the broad concept of "estimated value". The pixel intensity is a function of a characteristic of the portion of the region of interest determined by the segmentation mask. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, regarding Applicants argument on Page 15, Lines 26-27 and Page 16, Lines 1-2, Lee et al disclose that the blue band has the most discernment power and is the dominant spectral band.

Consequently, Claims 1, 14 and 44 are unpatentable in view of the teachings of Cabib et al, Lee et al and Bostock et al combination.

Regarding Applicants argument concerning Claims 2 and 3, the Examiner indicates that texture is a measure of smoothness and roughness of an image which is identified by the brightness of the pixels in the image. Figure 4 represents the histogram of all pixel intensities which include the intensity of lesion pixels as well.

Regarding Applicants argument concerning Claim 11, Bostock et al clearly disclose removal of hair structure and small blob-like regions. The only exception to Bostock et al teachings are the thick hairs that cross or touch the lesions which are not claimed.

Regarding Applicants argument concerning Claim 17, light emits from a substance after penetrating into the substance. Consequently, Cabib et al teachings regarding the light emitted from the sample reads claim limitation of "the light penetrates and re-emitted".

Regarding Applicants argument concerning Claims 19 and 55, Cabib et al disclose a spectral range of 400-1000 nm which includes near infrared (Column 19, Table I).

Regarding Applicants argument concerning Claim 20, Cabib et al disclose suppressing specular reflections prior to the digital imaging step (Column 28, Lines 22-36).

Regarding Applicants argument concerning Claim 21, Cabib et al teachings read the broad claim language of "non-uniformities of illumination".

The above responses also hold for Claims 21, 23-31 and 41.

Regarding Applicants argument concerning Claim 34, the Examiner asserts that Shindewolf et al calculates the center of gravity of the pixel values for lesion images. Calculation of the center of gravity is based on calculating the intensity moment of each pixel in the image.

Regarding Applicants argument concerning Claim 42, the Examiner asserts that the constraint of 100% sensitivity to melanoma is a theoretical concept and is achievable if the result of each of the infinite number of experiments prove 100% sensitivity. The result of 92.4% sensitivity to melanoma disclosed by Bostock is a reliable equivalent practical constraint.

Regarding Applicants argument concerning Claim 53, Cabib et al teachings read the broad claim language of "intercepting the **light** from the **light source**".

Regarding Applicants argument concerning Claims 10 and 65, the Examiner indicates that claim language does not limit the claimed invention to "in vivo" or "in vitro" specimen. Furthermore, the concepts of "invasive" or non-invasive" are broad concepts in medical diagnosis as disclosed by Tryggvason et al (prior art of record).

Insufficient Affidavit

4. The affidavit filed on February 10, 2000 is insufficient to overcome the rejection of Claim 42 based upon 35 U.S.C. 103(a) rejection as being unpatentable over Cabib et al further in view of Lee et al and Bostock et al as set forth in the last Office action because the constraint of 100% sensitivity to melanoma is a theoretical concept and is achievable if the result of each of the infinite number of experiments prove 100% sensitivity. The result of 92.4% sensitivity to melanoma disclosed by Bostock is a reliable equivalent practical constraint. Furthermore, the affidavit refers only to the constraint of 100% sensitivity to melanoma described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

Claim Objections, Improper Dependent Claims

5. Claims 37, 38, 39, 40 and 43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim. The new Claims 68-72, which are rewritten in independent form, include further limitations of Claims 37, 38, 39, 40 and 43 and all of the limitations of the base Claim 14.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3, 11, 12, 14-21, 23-31, 41, 42, 44-50, 53-58, 67 and 74-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U.S. 5,784,162) further in view of Lee et al (IEEE Paper, ISBN: 0-7803-2553-2) and Bostock et al (IEEE Paper, ISBN: 0-85296-573-7).

Regarding Claim 1, Cabib et al disclose a method of characterizing a skin lesion wherein the absorption and scattering of light in different spectral bands by the skin lesion is a function of the condition of the skin (Column 16, Lines 12-35), the method comprising:

illuminating a portion of the skin including the region of interest by light in at least three spectral bands, one of which is a blue spectral band (Column 8, Lines 3-11; Column 18, Lines 61-67, Column 19, Lines 1-24); digitally imaging a portion of the skin including the region of interest at the at least three spectral bands with the light re-emitted by the portion of the skin to generate digital images comprising digital signals whose values are a function of the condition of the region

of interest of the skin (Column 7, Lines 9-43; Column 7, Lines 60-64); providing the digital images to a processor (Figure 2; Column 17, Lines 1-45) and outputting the characterization of the condition of the skin as malignant or benign (Column 60, Lines 57-67, Column 61, Lines 1-17). Cabib et al do not explicitly and specifically disclose the details of image processing comprising:

segmenting the digital images by generating a single segmentation mask defining the boundary of the region of interest for each image from the digital image in the blue spectral band, without operator intervention;

automatically computing at least one estimated value for each digital image at each spectral band which is a function of a characteristic of the portion of the region of interest determined by the segmentation mask, without operator intervention.

Lee et al disclose a multi-stage segmentation method that segments the digital image by generating a single segmentation mask defining the boundary of the region of interest for each image from the digital image in the blue spectral band, without operator intervention (Page 603, Column 1, Lines 3-6; Page 604, Section V, Step 3. Lee et al disclose as the final step, generating a single segmentation mask in the blue band as the dominant band. Lee et al teachings read the claimed language and encompass the claimed invention by performing a single segmentation mask in the blue band in addition to the previous segmentation for removing random noise.);

automatically computes at least one estimated value for each digital image at each spectral band which is a function of a characteristic of the portion of the region of interest determined by the

segmentation mask, without operator intervention (Pages 603-604, Sections IV and V. The intensity values of the pixels for each digital image at each spectral band are reasonable interpretation of the broad concept of "estimated value". The pixel intensity is a function of a characteristic of the portion of the region of interest determined by the segmentation mask.); characterizes the condition of the normal skin and lesion based on the estimated values, without operator intervention (Page 604, Section VI); and outputs the characterization of the condition of the skin (Table I, Figures 5-7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al invention according to the teachings of Lee et al because it will provide better control over structured noise and provide more accurate and reliable interpretation of skin lesions diagnosis. Cabib et al and Lee et al inherently disclose characterizing the condition of the skin as malignant or benign based on the estimated values, without operator intervention. However, for further emphasis, the Examiner cites the teachings of Bostock et al. Bostock et al disclose a neural network based system for skin cancer diagnosis characterizing the condition of the skin as malignant or benign based on the estimated values, without operator intervention (Page 215, Abstract). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al and Lee et al combination according to the teachings of Bostock et al to characterize skin lesions without operator intervention because it will increase the diagnosis accuracy.

Regarding Claim 2, Lee et al further disclose the method of Claim 1, further comprising estimating at least one value which is a function of the texture of the region of interest (Page 604,

Paragraphs 1 and 2; Figure 4. Texture is a measure of smoothness and roughness of an image which is identified by the brightness of the pixels in the image). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al invention according to the teachings of Lee et al to estimate the texture of the region of interest for characterization of the skin lesions because it will provide reliable knowledge regarding the structure of skin lesions for further diagnosis.

Regarding Claim 3, Lee et al further disclose the method of Claim 2, wherein the computing step comprises estimating values which are statistical measures of local intensity variation in the digital images in each spectral band, which are a function of the texture of the region of interest (Page 602-604; Figure 4; Sections II and IV).

Regarding Claim 11, Lee et al further disclose the method of Claim 1, wherein the segmenting step comprises generating the segmentation mask from a digital image by: removing digital signals from the digital image which corresponds to hair structure; deriving a threshold from a multimodal histogram of intensity levels; iteratively applying the threshold to the digital signals of the digital image; and removing digital signals which correspond to small blob-like regions from the masked image (Pages 603-604, Section IV, Step 2). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al invention according to the teachings of Lee et al to eliminate hair structure and small blob-like regions from the masked image because it will provide more accurate information regarding the texture of lesions for further diagnosis.

Regarding Claim 12, Cabib et al further disclose the method of Claim 1, wherein the digital imaging step further comprises digitally imaging the region of interest with a digital camera (Column 28, Lines 13-16).

With regards to Claims 14-16, arguments analogous to those presented for Claim 1 are applicable to Claim 14-16. Regarding Claim 14, Lee et al further disclose the segmentation mask generated from the digital image acquired in that spectral band for which the imaged skin lesion has the largest area (Page 603, Column 1, Lines 3-6; Page 604, Column 2, Section V, Lines 2-8. The blue band has the most discernment power and is the dominant spectral band.)

Regarding Claim 17, Cabib et al further disclose the method of Claim 14, wherein the illuminating step further comprises illuminating the region of interest with light in at least one spectral band which penetrates the papillary dermis and re-emitted therefrom (Column 7, Lines 60-64. Light re-emits from the skin after penetrating into the papillary dermis.).

Regarding Claim 18, Cabib et al further disclose the method of Claim 17, wherein the digital imaging step further comprises digitally imaging the region of interest with a digital camera (Column 28, Lines 13-16).

Regarding Claim 19, Cabib et al further disclose the method of Claim 17, wherein the illuminating step further comprises illuminating the region of interest with light in a near infrared spectral band (Column 8, Lines 3-7; Column 19, table I).

Regarding Claim 20, Cabib et al further disclose the method of Claim 14, further comprising suppressing specular reflections prior to the digital imaging step (Column 28, Lines

22-36).

Regarding Claim 21, Cabib et al further disclose the method of Claim 1, wherein the processor converts the digital signals of each of the digital images into values corrected for non-uniformities of illumination and of response prior to the segmenting step (Column 27, Lines 22-55; Column 33, Lines 9-16).

Regarding Claim 23, Lee et al disclose the method of Claim 1, wherein the segmenting step further comprises segmenting the digital images by generating a segmentation mask in other spectral band (Page 603, Section III). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al invention according to the teachings of Lee et al because it will provide better control over structured noise and provide reliable interpretation of skin lesions diagnosis.

Regarding Claim 24, Cabib et al disclose the method of Claim 14, wherein the segmenting step comprises generating the mask at the shortest available wavelength (Figure 27 (a), 27 (b) and 27 (c); Column 54, Lines 6-61).

Regarding Claim 25, Cabib et al disclose the method of Claim 14, wherein the illuminating step comprises illuminating the region of interest by light at least one spectral band whose center is between about 400 to about 500 nanometers, and the segmentation step comprises generating the mask from a digital image at the spectral band between about 400 to about 500 nanometers (Column 27, Line 67, Column 28, Lines 1-8; Figure 27 (a), 27 (b) and 27 (c); Column 54, Lines 6-61).

With regards to Claim 26, arguments analogous to those presented for Claim 11 are applicable to Claim 26.

Regarding Claim 27, Lee et al further disclose the method of Claim 16, wherein the segmenting step comprises generating the segmentation mask by comparing estimated values which are a function of the textures within the digital images with a threshold (Pages 603-604, Section IV).

Regarding Claim 28, Lee et al further disclose the method of Claim 27, further comprising generating the segmentation mask by comparing estimated texture values to a threshold derived through statistical analysis of each digital image (Pages 603-604, Sections IV and V).

Regarding Claim 29, Lee et al further disclose the method of Claim 14, wherein the computing step comprises estimating at least one value which is a function of the texture of the region of interest determined by the segmentation mask (Page 604, Paragraphs 1 and 2; intensity value S).

Regarding Claim 30, Lee et al further disclose the method of Claim 29, wherein the computing step further comprises estimating values which are a function of the texture of the region of interest determined by the segmentation mask separately in each spectral band, based on the same segmentation mask (Pages 603-604; Figure 4; Sections III and IV).

Regarding Claim 31, Lee et al further disclose the method of Claim 29, wherein the computing step comprises estimating values which are statistical measures of local intensity variation in the digital images in each spectral band which are a function of the texture (Pages

603-604; Figure 4; Sections III and IV).

Regarding Claim 41, Lee et al further disclose the method of Claim 14, wherein the characterizing step comprises comparing a weighted combination of estimated values against a threshold value (Pages 602-604, Sections II, III and IV. The method considers more weight for blue band.).

Regarding Claim 42, Cabib et al and Lee et al do not disclose the method of Claim 14, wherein the condition of the region of interest to be characterized is the presence of a melanoma and weight coefficients for each estimated value and the threshold value are selected to maximize specificity, under the constraint of a defined sensitivity to melanoma, on a representative set of training images. Bostock et al further disclose the application of multi-layer perceptron to the diagnosis of skin melanoma, wherein the condition of the region of interest to be characterized is the presence of a melanoma and weight coefficients for each estimated value and the threshold value are selected to maximize specificity, under the constraint of maximum sensitivity to melanoma, on a representative set of training images (Page 216, Standard MPL; Tables 1-4). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al and Lee et al combination according to the teachings of Bostock et al to provide a reasonable defined sensitivity to melanoma, on a representative set of training images because it will provide more reliable classification for skin lesions diagnosis.

Regarding Claim 73, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 42, wherein the defined sensitivity to melanoma on a representative set of training images is

100%. Examiner takes Official Notice that the constraint of 100% sensitivity to melanoma is a theoretical concept and is achievable if the result of each of the infinite number of experiments prove 100% sensitivity. The result of 92.4% sensitivity to melanoma disclosed by Bostock is a reliable equivalent practical constraint.

With regards to Claim 44, arguments analogous to those presented for Claims 1 and 14 are applicable to Claim 44.

With regards to Claim 45, arguments analogous to those presented for Claim 20 are applicable to Claim 45.

With regards to Claim 46, arguments analogous to those presented for Claim 21 are applicable to Claim 46.

Regarding Claim 47, Cabib et al further disclose the system of Claim 44, wherein the digital processor is coupled to the source of illumination and to the camera for controlling the intensity of illumination and exposure time, respectively (Column 28, Lines 9-16).

With regards to Claim 48, arguments analogous to those presented for Claim 23 are applicable to Claim 48.

With regards to Claim 49, arguments analogous to those presented for Claim 30 are applicable to Claim 49.

With regards to Claim 50, arguments analogous to those presented for Claim 41 are applicable to Claim 50.

Regarding Claim 53, Cabib et al further disclose the system of Claim 44, wherein the filter

means comprises a plurality of interference filters mounted on a wheel for stepping any filter into a position intercepting the light from the light source (Column 27, Line 67, Column 28, Lines 1-8).

With regards to Claim 54, arguments analogous to those presented for Claim 25 are applicable to Claim 54.

Regarding Claim 55, Cabib et al further disclose the system of Claim 54, wherein the set of interference filters includes a filter whose center lies in at least one spectral band in the near infra red range whose center lies between about 750 and 1000 nanometers (Figures 4 and 5; Column 20, Lines 31-62).

With regards to Claim 56, arguments analogous to those presented for Claim 47 are applicable to Claim 56.

With regards to Claim 57, arguments analogous to those presented for Claim 56 are applicable to Claim 57. Cabib et al furthermore disclose the source of illumination providing broad-band ("white") light and the camera detect light in a plurality of spectral bands between the near ultraviolet to near infrared (Column 8, Lines 3-7; Figures 4 and 5; Column 20, Lines 31-62).

With regards to Claim 58, arguments analogous to those presented for Claim 3 are applicable to Claim 58.

With regards to Claim 67, arguments analogous to those presented for Claim 1 are applicable to Claim 67.

Regarding Claim 74, Cabib et al disclose the method of Claim 1, where the

characterization step is based on a linear combination of the estimated values (Column 9, Lines 62-67, Column 10, Lines 1-16).

Regarding Claim 75, Cabib et al disclose the method of Claim 1, where the characterization step is based on a non-linear combination of the estimated values (Column 10, Lines 27-33; Column 21, Lines 4-42, Formulas 4-6. Optical density is a non-linear (logarithmic) function utilized in characterization of skin lesions based on non-linear combination of the spectral cubes estimated values.).

Regarding Claim 76, Cabib et al disclose the method of Claim 1, where the characterization step is based on a sequential combination of applying a linear combination of the estimated values and a non-linear combination of the estimated values(Column 9, Lines 62-67, Column 10, Lines 1-16).

With regards to Claims 77-79, arguments analogous to those presented for Claims 74-76 are applicable to Claims 77-79, respectively.

8. Claims 7, 32-36, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U.S. 5,784,162) further in view of Lee et al (IEEE Paper, ISBN: 0-7803-2553-2), Bostock et al (IEEE Paper, ISBN: 0-85296-573-7) and Schindewolf et al (Journal of the American Academy of Dermatology, 0190-9622).

Regarding Claim 7, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 1, wherein the computing step further comprises estimating a value which is a function of the blotchiness of the segmented image. Schindewolf et al disclose evaluation of image

acquisition techniques for diagnosing malignant melanoma wherein the computing step further comprises estimating a value which is a function of the blotchiness of the segmented image (Figures 1, 3-6; Page 36, Digital Image Processing. As indicated in description of Figure 6, number of end points are used for calculation of irregularity of the lesion.). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Cabib et al, Lee et al and Bostock et al combination according to the teachings of Schindewolf et al because irregularity of the lesion is another important feature for classification of benign and malignant lesions.

With regards to Claims 32 and 33, arguments analogous to those presented for Claim 6 are applicable to Claim 32 and 33.

Regarding Claim 34, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 33, wherein the computing step further comprises computing the intensity moment with a binary intensity distribution. Schindewolf et al disclose evaluation of image acquisition techniques for diagnosing malignant melanoma wherein the computing step further comprises computing the intensity moment with a binary intensity distribution (Figures 1, 3-6; Page 36, Digital Image Processing. As indicated in description of Figure 4, the distance between three color centers and center of gravity (S) are used for calculation of intensity moment.). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al, Lee et al and Bostock et al combination according to the teachings of Schindewolf et al because intensity moment is an important feature for classification of benign and malignant lesions.

Regarding Claim 35, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 14, wherein the computing step further comprises estimating at least one value which is a function of the blotchiness of the segmented digital image. Schindewolf et al disclose evaluation of image acquisition techniques for diagnosing malignant melanoma wherein the computing step further comprises estimating at least one value which is a function of the blotchiness of the segmented image, the estimated blotchiness value being defined through statistical properties of the spatial distribution of topographic regions of the segmented digital image at each spectral band (Figures 1, 3-6; Page 36, Digital Image Processing. As indicated in description of Figure 6, number of end points are used for calculation of irregularity of the lesion.). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al, Lee et al and Bostock et al combination according to the teachings of Schindewolf et al because irregularity of the lesion is another important feature for classification of benign and malignant lesions.

Regarding Claim 36, Schindewolf et al further disclose the method of Claim 35, wherein the computing step further comprises determining the centroid of topographic regions of the segmented digital image at each spectral band (Figures 1, 3-6; Page 36, Digital Image Processing. As indicated in description of Figures 5 and 6, the centroids of topographic regions of the segmented digital image at each spectral band are being considered in classification of skin lesions). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al, Lee et al and Bostock et al combination according

to the teachings of Schindewolf et al because determining the centroids of topographic regions of the segmented digital image at each spectral band in calculating the irregularity of the skin lesions will improve the result of evaluation for classification of benign and malignant lesions.

With regards to Claim 61, arguments analogous to those presented for Claim 6 are applicable to Claim 61.

With regards to Claim 62, arguments analogous to those presented for Claim 7 are applicable to Claim 62.

9. Claims 10 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U.S. 5,784,162) further in view of Lee et al (IEEE Paper, ISBN: 0-7803-2553-2), Bostock et al (IEEE Paper, ISBN: 0-85296-573-7) and Tryggvason et al (U.S. 5,660,982).

Regarding Claim 10, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 1, further comprising characterizing the type of lesion as invasive or non-invasive. Tryggvason et al disclose identification, diagnosis, monitoring and treatment of invasive cells comprising characterizing the type of lesion as invasive or non-invasive (Figure 2; Column 13, Lines 1-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al, Lee et al and Bostock et al combination according to the teachings of Tryggvason et al because it will provide essential information for assessment of the appropriate treatment.

With regards to Claim 65, arguments analogous to those presented for Claim 10 are applicable to Claim 65.

10. Claims 13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U.S. 5,784,162) further in view of Lee et al (IEEE Paper, ISBN: 0-7803-2553-2), Bostock et al (IEEE Paper, ISBN: 0-85296-573-7) and Herbin et al (IEEE transaction on Medical Imaging ISSN: 0278-0062).

Regarding Claim 13, Cabib et al, Lee et al and Bostock et al do not disclose the method of Claim 11, further comprising:

photographing the region of interest with a color camera to form color photographic slides; and illuminating the color photographic slides with light in each spectral band; wherein the digital imaging step comprises digitally imaging the illuminated color photographic slides of the region of interest with a digital camera. Herbin et al disclose color quantitation through image processing in dermatology comprising:

photographing the region of interest with a color camera to form color photographic slides; and illuminating the color photographic slides with light in each spectral band; wherein the digital imaging step comprises digitally imaging the illuminated color photographic slides of the region of interest with a digital camera (Figure 1; Section II, Acquisition System; Section VI, Discussion and Conclusion). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al , Lee et al and Bostock et al combination according to the teachings of Herbin et al because it will expand versatility of the system by utilizing photographic slides as an additional image recording medium.

With regards to Claim 22, arguments analogous to those presented for Claim 13 are

applicable to Claim 22.

11. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabib et al (U.S. 5,784,162) further in view of Lee et al (IEEE Paper, ISBN: 0-7803-2553-2), Bostock et al (IEEE Paper, ISBN: 0-85296-573-7) and Page (U.S. 5,157,461).

Regarding Claim 51, Cabib et al further disclose the system of Claim 44 wherein the camera records monochromatic images (Column 20, Lines 31-35). Cabib et al, Lee et al and Bostock et al do not disclose the system of Claim 44, wherein the illumination means comprises: a tungsten halogen light source with feedback to stabilize the intensity in each wavelength band; means for sequentially filtering the light; and an optical fiber ring illuminator to distribute the filtered light. Page discloses an optical rate sensor apparatus comprising a light source with feedback to stabilize the intensity in each wavelength band (Figures 30-32, 35-39; Column 55, Lines 65-68, Column 59, Lines 1-46); means for sequentially filtering the light (Figure 14; Column 48, Lines 14-57); and an optical fiber ring illuminator to distribute the filtered light (Figure 12; Column 30, Lines 50-68, Column 31, Lines 1-45). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to to modify Cabib et al, Lee et al and Bostock et al inventions according to the teachings of Page because this configuration is the conventional system for diagnosis or microsurgery.

Regarding Claim 52, Page further discloses an optical rate sensor apparatus comprising a feedback loop for stabilizing the intensity of the light source by the processor (Figures 30-32, 35-39; Column 55, Lines 65-68, Column 59, Lines 1-46).

Allowable Subject Matter

12. Claims 6 and 68-72 are allowable.

Claim 6 recites a method of characterizing skin lesion comprising estimating asymmetry of the region of interest in each spectral band, for two principal axes of the segmented image by computing the normalized sum of the absolute values of differences in intensity between each pair of pixels whose locations, with respect to a principal axis, are mirror image of each other.

Claim 68 recites a method of characterizing skin lesion including the computing step comprises estimating a value which is a statistical measure of the deviation of the segmentation mask from the border of an ellipse of the same area, aspect ratio, and orientation as the segmentation mask.

Claim 69 recites a method of characterizing skin lesion including the computing step comprises estimating a statistical measure of the gradient values of the intensity of the digital images across the border of the segmented images, at each spectral band.

Claim 70 recites a method of characterizing skin lesion including the computing step comprises estimating values based on the ratio of standard deviation of the areas of dermal papillae to their mean within the segmentation mask.

Claim 71 recites a method of characterizing skin lesion including the computing step comprises estimating values of the average and standard deviation of the thickness of rete ridges within the segmentation mask.

Claim 72 recites a method of characterizing skin lesion comprising calibrating each pixel

location in the digital image in each spectral band with respect to the stored images of a white target material having known diffuse reflectance, each of the stored images being an average of a plurality of images acquired at each spectral band, while the material undergoes continual in-plane motion.

The features identified in Claims 6 and 68-72, in combination, are neither disclosed nor suggested by the prior arts of record.

13. Claims 4, 5, 8, 9, 59, 60, 63 and 64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 4 recites the method of Claim 2, wherein the computing step comprises estimating values based on the ratio of standard deviation of the areas of dermal papillae to their mean within the segmentation mask.

Claim 5 recites the method of Claim 2, wherein the computing step comprises estimating values of the average and standard deviation of the thickness of rete ridges within the segmentation mask.

Claim 8 recites the method of Claim 1, further comprising estimating at least one value which is a function of the irregularity of the border of the region of interest by estimating a value which is a statistical measure of the deviation of the segmentation mask from the border of an ellipse of the same area, aspect ratio, and orientation as the segmentation mask.

Claim 9 recites the method of Claim 1, further comprising estimating a value which is a

function of the gradient at the border of the region of interest estimating a statistical measure of the gradient values of the intensity of the digital images across the border of the segmented images, at each spectral band.

Claims 59, 60, 63 and 64 recite the system corresponding to the method of characterization of lesions on skin disclosed in Claims 4, 5, 8 and 9, respectively, and are therefore allowable.

The features identified in Claims 4, 5, 8, 9, 37-40, 43, 59, 60, 63 and 64 in combination with the other elements of the base claims are neither disclosed nor suggested by the prior arts of record.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mehrdad Dastouri whose telephone number is (703) 305-2438. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au, can be reached at (703)308-6604.

Any response to this action should be **mailed** to:

Commissioner for Patents and trademarks
Washington, D.C. 20231

or **faxed** to:

(703) 308-9051, or (703) 308-9052 (for ***formal*** communications; please mark **"EXPEDITED PROCEDURE"**)

(703) 306-5406 (for ***informal*** or ***draft*** communications, please label "PROPOSED" or "DRAFT")

Hand delivered responses should be brought to:

Crystal Park II, 2121 Crystal Drive,
Arlington, VA., Sixth Floor (Receptionist).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703)305-3900.

MD

Mehrdad Dastouri
Patent Examiner
Group Art Unit 2723
April 21, 2000

Amelia Au
Supervisory Patent Examiner
Technology Center 2700